UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

MARIA LUISA FLORES, INDIVIDUALLY AND AS REPRESENTATIVES OF THE ESTATE OF RAMON G. FLORES, SR.; ALANNA FLORES BLANCO, INDIVIDUALLY AND AS REPRESENTATIVES OF THE ESTATE OF RAMON G. FLORES, SR.; RAMON G. FLORES, JR., INDIVIDUALLY AND AS REPRESENTATIVES OF THE ESTATE OF RAMON G. FLORES, SR.; AND ESTATE OF RAMON G. FLORES SR.,

Plaintiffs,

v.

THORATEC LLC,

Defendant.

Case No. SA-23-CV-01093-JKP

MEMORANDUM OPINION AND ORDER

Before the Court is Defendant Thoratec LLC's Motion to Dismiss pursuant to Fed. R. Civ. P. 12(b)(6). *See* ECF No. 14. Plaintiff Maria Luisa Flores, et al. (hereinafter "Flores") responded to the motion and Thoratec replied to the response. *See* ECF Nos. 18, 19. The motion is fully briefed and ripe for ruling. After due consideration of the parties' briefings, legal arguments, and the applicable law, the Court finds Flores has met her pleading burden and, therefore, **DENIES** the motion. *See* ECF No. 14.

BACKGROUND

This case arises from the September 10, 2021 death of Ramon G. Flores, Sr. *See* ECF No. 15 (First Amended Complaint). When he died, Flores was 76 years old and had lived for years

with congestive heart failure and end-stage ischemic cardiomyopathy, which is a condition where weakened heart muscle struggles to pump blood effectively, leading to shortness of breath and fatigue. *Id*. at ¶ 39. On August 25, 2021, Flores presented at the Emergency Department of Methodist Hospital in San Antonio with worsening shortness of breath. *Id*. After several days at Methodist Hospital, Flores was approved for implantation of a HeartMate 3™ Left Ventricular Assist Device (hereinafter "HeartMate 3"). *Id*. The surgery to implant the HeartMate 3 took place on September 2, 2021 and was performed by cardiothoracic surgeon Masahiro Ono, M.D. and assisting surgeon Masaki Funamoto, M.D. *Id*. at ¶ 41.

According to the Amended Complaint, the HeartMate 3 device initially implanted into Flores' chest (the "Subject HeartMate 3") was defective. During surgery, a large amount of air was observed entering Flores' left ventricle and aortic root from the left ventricular apex area where the Subject HeartMate 3 had been attached to his heart. *Id*. at ¶ 45. After placing Flores back on cardiopulmonary bypass, Dr. Ono re-evaluated the pump and repaired a previously damaged right atrial appendage. *Id*. at ¶ 46. Flores was then slowly weaned from bypass, the Subject HeartMate 3 was restarted, and pump speed was gradually increased. *Id*. at ¶¶ 46–47. Again, Dr. Ono observed significant air entering the left ventricle and aortic root which he felt was being suctioned into the pump at the interface between the apical cuff and the pump body. *Id*. at ¶ 47. Dr. Ono therefore decided to remove the Subject HeartMate 3 and replace it with a new HeartMate 3 device. *Id*. at ¶ 48. After implanting the replacement HeartMate 3, no air was seen entering the left ventricle from the apical cuff-pump interface. *Id*.

Head CT scans taken after the surgery revealed that Flores had suffered frontal lobe infarctions resulting from air emboli during the procedure. *Id*. at ¶ 52. Unfortunately, Flores

never regained consciousness. After consultation with his care team, the Flores family decided to withdraw supportive care, and Flores died on September 10, 2021. *Id*. at ¶ 52–54.

Dr. Ono examined the explanted Subject HeartMate 3 after surgery and concluded that the device had a "mechanical issue" that prevented the pump from properly attaching to the apical cuff. *Id*. at ¶ 51. He then returned the Subject HeartMate 3 to Defendant Thoratec so that it could conduct its own post-clinical use inspection. A visual inspection of the cuff lock by Defendant's engineers confirmed that at least one of the locking arms on the cuff lock was "bent." *Id*. at ¶ 55. A dimensional inspection of the cuff lock by Defendant's engineers then confirmed that both locking arms of the cuff lock were "damaged" and "bent out of specification." *Id*. In other words, the locking arms of the cuff lock installed into the Subject HeartMate 3 deviated from the dimensional specifications approved by the FDA during the Premarket Approval ("PMA") process.

Members of Flores' estate brought the case at bar, alleging Thoratec's negligence, gross negligence, and strict liability based on its alleged breach of its duty to manufacture the HeartMate 3 in accordance with the dimensional and process specifications approved by the FDA. *Id*. at ¶¶ 57–63 (negligence); ¶¶ 65–72 (gross negligence); ¶¶ 74–81 (strict liability-manufacturing defect). Thoratec brings the instant motion, arguing Flores' causes of action are expressly and impliedly preempted under the Federal Food Drug and Cosmetic Act (FDCA). For the reasons discussed herein, the Court disagrees, finding Flores has sufficiently alleged a viable parallel claim.

LEGAL STANDARD

To provide opposing parties fair notice of the asserted cause of action and the grounds upon which it rests, every pleading must contain a short and plain statement of the cause of

action which shows the pleader is entitled to relief. Fed. R. Civ. P. 8(a)(2); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). To satisfy this requirement, the complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 555–558, 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The focus is not on whether the plaintiff will ultimately prevail, but whether that party should be permitted to present evidence to support adequately asserted causes of action. *Id.*; *Twombly*, 550 U.S. at 563 n.8. Thus, to warrant dismissal under Federal Rule 12(b)(6), a complaint must, on its face, show a bar to relief or demonstrate "beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Fed. R. Civ. P. 12(b)(6); *Clark v. Amoco Prod. Co.*, 794 F.2d 967, 970 (5th Cir. 1986). Dismissal "can be based either on a lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." *Frith v. Guardian Life Ins. Co.*, 9 F. Supp.2d 734, 737–38 (S.D.Tex. 1998). "Thus, the court should not dismiss the claim unless the plaintiff would not be entitled to relief under any set of facts or any possible theory that he could prove consistent with the allegations in the complaint." *Jones v. Greninger*, 188 F.3d 322, 324 (5th Cir. 1999) *Vander Zee v. Reno*, 73 F.3d 1365, 1368 (5th Cir. 1996).

In assessing a motion to dismiss under Federal Rule 12(b)(6), the court's review is limited to the live Complaint and any documents attached to it. *Brand Coupon Network, L.L.C. v. Catalina Mktg. Corp.*, 748 F.3d 631, 635 (5th Cir. 2014). The court may also consider documents attached to either a motion to dismiss or an opposition to that motion when the documents are referred to in the pleadings and are central to a plaintiff's claims. *Id.* When reviewing the Complaint, the "court accepts all well-pleaded facts as true, viewing them in

the light most favorable to the plaintiff." *Martin K. Eby Constr. Co. v. Dallas Area Rapid Transit*, 369 F.3d 464, 467 (5th Cir. 2004) (quoting *Jones v. Greninger*, 188 F.3d at 324).

A Complaint should only be dismissed under Rule 12(b)(6) after affording ample opportunity for the plaintiff to state a claim upon which relief can be granted, unless it is clear amendment would be futile. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *Hitt v. City of Pasadena*, 561 F.2d 606, 608–09 (5th Cir. 1977); *DeLoach v. Woodley*, 405 F.2d 496, 496–97 (5th Cir. 1968). Consequently, when it appears a more careful or detailed drafting might overcome the deficiencies on which dismissal is sought, a Court must allow a plaintiff the opportunity to amend the Complaint. *Hitt*, 561 F.2d at 608–09. A court may appropriately dismiss an action with prejudice without giving an opportunity to amend if it finds the plaintiff alleged his best case or if amendment would be futile. *Foman*, 371 U.S. at 182; *DeLoach*, 405 F.2d at 496–97.

ANALYSIS

Thoratec argues Flores' complaint should be dismissed because the claims alleged are preempted by federal law. Specifically, Thoratec argues the HeartMate 3's Premarket Approval (PMA) triggers express preemption under 21 U.S.C. § 360k(a) as interpreted by *Riegel v. Medtronic*, 552 U.S. 312 (2008), which bars Flores from bringing suit under a state-law requirement that is different from, or in addition to, those required by federal law. *See Riegel*, 552 U.S. at 326–29. Thoratec further argues, to the extent Flores seeks to enforce the FDCA or the FDA's implementing regulations, those claims are impliedly preempted pursuant to *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001), and the FDCA's "no private right of action clause." *See* 21 U.S.C. § 337(a). Thoratec finally argues Flores' claims do not fit through the "narrow gap" between express and implied preemption that the application of *Riegel*

and *Buckman* create. *Gates v. Medtronic, Inc.*, 192 F. Supp. 3d 704, 711 n.7 (W.D. Tex. 2016), quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010). However, the Court finds Flores' claims do fit the narrow gap between express and implied preemption, and Thoratec's express and implied preemption arguments are therefore unavailing.

The Fifth Circuit has recognized plaintiffs may allege a "parallel claim" not preempted by the FDCA by alleging a defendant failed to comply with FDA-approved manufacturing specifications and those failures caused injury. *See Bass v. Stryker Corp.*, 669 F.3d 501, 512 (5th Cir. 2012). District courts in the Fifth Circuit have allowed manufacturing defect claims to proceed where the plaintiff pled with sufficient specificity how a device deviated from its PMA specifications. *See e.g., Yosowitz v. Covidien L.P.*, 182 F. Supp. 3d 683, 690. In *Funk*, the Fifth Circuit held that to survive a preemption-based motion to dismiss, a complaint must "specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury." *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011). In other words, the complaint should set forth "how the manufacturing process failed." *Id*. Several years later in *Bass*, the Fifth Circuit clarified its approach when it declined to require the plaintiff to identify the exact FDA regulations that had allegedly been violated when the defendant manufactured his prosthetic hip, instead holding that fact-based, non-conclusory pleadings were sufficient to state a parallel claim under *Funk*. 669 F.3d at 510.

Moreover, *Funk* is distinguishable from the case at bar. In *Funk*, the Fifth Circuit found the complaint to be "impermissibly conclusory and vague" because it "relies on *res ipsa loquitur* to suggest only that the 'that the thing speaks for itself.'" *Funk v. Stryker Corp.*, 631 F.3d at 782. Here, Flores does not rely on *res ipsa loquitur*, but rather specifically alleges Thoratec's own

engineers, upon visual inspection, confirmed at least one of the Subject HeartMate 3's locking arms on the cuff lock was "bent." Flores further alleges Thoratec's engineers conducted a dimensional inspection of the cuff lock, confirming both locking arms of the cuff lock were "damaged" and "bent out of specification." In other words, the locking arms of the cuff lock installed into the Subject HeartMate 3 deviated from the dimensional specifications approved by the FDA. Flores alleges Thoratec was required under the FDCA to manufacture the HeartMate 3 according to the following specifications, among others:

- Install a cuff lock into the HeartMate 3 motor assembly that meets the dimensional specifications approved by the FDA;
- Install a cuff lock into the HeartMate 3 motor assembly with locking arms that are symmetrical and not bent out of FDA-approved specification;
- Manufacture the HeartMate 3 in accordance with the process specifications or "manufacturing steps" approved by the FDA;
- Manufacture the HeartMate 3 so that a hermetic and hemostatic seal is created and maintained between the pump assembly and the apical cuff attached to the left ventricle; and
- Manufacture the HeartMate 3 so that air is not drawn into the pump at the interface between the pump assembly and the apical cuff during pump operation and entrained within the left ventricle.

See ECF No. 13 at ¶ 36. Flores alleges the decedent's Subject HeartMate 3 deviated from these federal requirements in the following ways:

- When pump speed was increased, "significant air was seen on TEE in the left ventricle and aortic root. Dr. Ono was concerned that air was being suctioned from the interface between the apical cuff and pump body." *Id.* at ¶ 47.
- Dr. Ono examined the explanted Subject HeartMate 3 on the back table and concluded that the device had a "mechanical issue" that prevented the pump from attaching to the apical cuff. *Id.* at ¶ 51.
- Visual inspection of the Subject Cuff Lock by Thoratec's engineers confirmed that one of the locking arms was "bent." Measurements taken of the Subject Cuff Lock by Thoratec's engineers confirmed that both locking arms of the Subject Cuff Lock were "damaged" and "bent out of specification;" that is, the locking arms of the Subject Cuff Lock deviated from the dimensional specifications approved by the FDA during the PMA process." *Id.* at ¶ 55.
- Thoratec's manufacture and assembly of the Subject HeartMate 3 deviated from FDA-approved manufacturing steps and process specifications. *Id.* at ¶ 61(d).
- Thoratec's assembly and quality assurance personnel failed to properly inspect the Subject HeartMate 3 as required by the FDA-approved manufacturing process specifications. *Id.* at ¶ 61(f).

Flores further alleges these deviations from the FDA-approved manufacturing process resulted in air entrainment in the decedent's left ventricle, air embolization to his brain, and his eventual death. *Id.* at ¶ 62. Based on these allegations, the Court finds, consistent with district courts assessing similar claims, Flores has alleged a quintessential parallel claim. *See e.g. Edwards v. Thoratec LLC*, 532 F. Supp. 3d 786 (D. Minn. 2021).

The Fifth Circuit recognized in *Bass* that "courts must keep in mind that much of the product-specific information about manufacturing needed to investigate a medical device claim fully is kept confidential by federal law." *Id.* at 511 (citing *Bausch*, 630 F.3d at 558). As a result, asking plaintiffs to make specific allegations regarding a defendant's manufacturing process "may make pleading a parallel claim regarding defective manufacturing nearly impossible." *Id.* (citing *See In re Medtronic*, 623 F.3d at 1209 (Melloy, J., dissenting)). The Court therefore finds, consistent with the Fifth Circuit's finding in *Bass*, that at this early stage, Flores has successfully alleged Thoratec's manufacturing was conducted in violation of the applicable federally-mandated standards and resulted in the manufacturing defects giving rise to Flores' state law claims.

Because Flores has identified "how the manufacturing process failed" and alleged the FDA-approved PMA requirements for the HeartMate 3 were violated during assembly and manufacture of the Subject HeartMate 3, Flores has met her burden at the pleading stage of the litigation. Flores will have to proffer sufficient evidence to support her allegations at a later stage of the litigation, after discovery has been conducted.

CONCLUSION

For the reasons discussed, the Court finds Flores has met her pleading burden and, therefore, **DENIES** Thoratec's Motion to Dismiss. *See* ECF No. 14

It is so ORDERED.
SIGNED this 22nd day of May, 2024.

JASON PULLIAM
UNITED STATES DISTRICT JUDGE